

AMENDMENT TO GLP TEST PROTOCOL

Amendment No.: 3
Effective Date: October 29, 2008
Sponsor: Summit Brands
7201 Engle Road
Fort Wayne, IN 46804-2228
Sponsor Representative: Wagner Regulatory Associates
P.O. Box 640
Hockessin, DE 19707-0640
Test Facility: ATS Labs
1285 Corporate Center Drive, Suite 110
Eagan, MN 55121
Protocol Title: Standard Test Method for Efficacy of Sanitizers
Recommended for Inanimate Non-Food Contact
Stainless Steel Surfaces
ATS Labs Protocol Number: WRA01021808.NFS
ATS Labs Project Number: A06368

Modifications to Protocol:

- 3a. Per Sponsor's request, the protocol is amended to change the lot/batch numbers as well as the 60 day old lots. The following lots are equivalent and will be reported as the second name listed:

Lot # 03050UP48 reported as Lot 03050UP48 (≥60 days old)
Lot # 03050UP49 reported as Lot 03050UP49 (≥60 days old)
Lot # 005 reported as Lot 07323UP301 (Batch 005)
Lot 06 reported as Lot 8182UP164 (Batch 06)

- 3b. Due to a typographical error, this protocol is amended to correct the protocol title in amendment 1 and amendment 2 to Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Stainless Steel Surfaces.

Changes to the protocol are acceptable as noted.

Study Director



Date

10/29/08

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INITIALS jm DATE 11-4-08



AMENDMENT TO GLP TEST PROTOCOL

Amendment No.: 2

Effective Date: July 29, 2008

Sponsor: Summit Brands
7201 Engle Road
Fort Wayne, IN 46804-2228

Sponsor Representative: Wagner Regulatory Associates
P.O. Box 640
Hockessin, DE 19707-0640

Test Facility: ATS Labs
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Protocol Title: Standard Test Method for Efficacy of Sanitizers
Recommended for Inanimate Non-Food Contact
Surfaces


ATS Labs Protocol Number: WRA01021808.NFS

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
Modifications to Protocol:

Per Sponsor's request, the protocol is amended to change the test substance to be used in repeat testing from Lot 005 to Lot 06.

Changes to the protocol are acceptable as noted.


Study Director

7-29-08
Date

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AMENDMENT TO GLP TEST PROTOCOL

Amendment No.: 1

Effective Date: July 3, 2008

Sponsor: Summit Brands
7201 Engle Road
Fort Wayne, IN 46804-2228

Sponsor Representative: Wagner Regulatory Associates
P.O. Box 640
Hockessin, DE 19707-0640

Test Facility: ATS Labs
1285 Corporate Center Drive, Suite 110
Eagan, MN 55121

Protocol Title: Standard Test Method for Efficacy of Sanitizers
Recommended for Inanimate Non-Food Contact
Surfaces


ATS Labs Protocol Number: WRA01021808.NFS

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
Modifications to Protocol:


- 1a. This protocol is amended to allow repeat testing of Lot 005 against *Staphylococcus aureus* due to sporadic growth in the test resulting in scientifically unreasonable results.
- 1b. Per Sponsor's request, this protocol is amended to confirm test results of Lot 005 against *Klebsiella pneumoniae*.

Changes to the protocol are acceptable as noted.


Study Director

7-3-08
Date

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(For Laboratory Use Only)
ATS Labs Project #  06368

ATS LABS

PROTOCOL

06/16/08

**Standard Test Method for Efficacy of Sanitizers
Recommended for Inanimate Non-Food Contact Stainless Steel Surfaces**

Test Organisms:

Staphylococcus aureus (ATCC 6538)
Klebsiella pneumoniae (ATCC 4352)

PROTOCOL NUMBER

WRA01021808.NFS

PREPARED FOR

Summit Brands
7201 Engle Road
Fort Wayne, IN 46804-2228

SPONSOR REPRESENTATIVE

Wagner Regulatory Associates
P.O. Box 640
Hockessin, DE 19707-0640

PERFORMING LABORATORY


ATS Labs
1285 Corporate Center Drive, Suite 110
Eagan, MN 55121

PREPARED BY

Becky Lien, B.A.
Research Scientist I

DATE

February 18, 2008
Revised: May 15, 2008

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INITIALS  DATE 11-4-08

PROPRIETARY INFORMATION

THIS DOCUMENT IS THE PROPERTY OF AND CONTAINS PROPRIETARY INFORMATION OF ATS LABS. NEITHER THIS DOCUMENT, NOR INFORMATION CONTAINED HEREIN IS TO BE REPRODUCED OR DISCLOSED TO OTHERS, IN WHOLE OR IN PART, NOR USED FOR ANY PURPOSE OTHER THAN THE PERFORMANCE OF THIS WORK ON BEHALF OF THE SPONSOR, WITHOUT PRIOR WRITTEN PERMISSION OF ATS LABS.

Protocol Number: WRA01021808.NFS
Revised: May 15, 2008

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**Standard Test Method for Efficacy of Sanitizers
Recommended for Inanimate Non-Food Contact Stainless Steel Surfaces**

SPONSOR: Summit Brands
7201 Engle Road
Fort Wayne, IN 46804-2228

SPONSOR REPRESENTATIVE: Wagner Regulatory Associates
P.O. Box 640
Hockessin, DE 19707-0640

TEST FACILITY: ATS Labs
1285 Corporate Center Drive, Suite 110
Eagan, MN 55121

PURPOSE

The purpose of this assay is to evaluate the antimicrobial efficacy of sanitizers on pre-cleaned or lightly soiled inanimate, nonporous, non-food contact surfaces.

TEST SUBSTANCE CHARACTERIZATION

Test substance characterization as to content, stability, etc., (40 CFR, Part 160, Subpart F [160.105]) is the responsibility of the Sponsor. The test substance shall be characterized by the Sponsor prior to the experimental start date of this study. Pertinent information, which may affect the outcome of this study, shall be communicated in writing to the Study Director upon sample submission to ATS Labs.

SCHEDULING AND DISCLAIMER OF WARRANTY

Experimental start dates are generally scheduled on a first-come/first-serve basis once ATS Labs receives the Sponsor approved/completed protocol, signed fee schedule and corresponding test substance(s). Based on all required materials being received at this time, the proposed experimental start date is May 30, 2008. Verbal results may be given upon completion of the study with a written report to follow on the proposed completion date of June 26, 2008. To expedite scheduling, please be sure all required paperwork and test substance documentation is complete/accurate upon arrival at ATS Labs.

If a test must be repeated, or a portion of it, due to failure by ATS Labs to adhere to specified procedures, it will be repeated free of charge. If a test must be repeated, or a portion of it, due to failure of internal controls, it will be repeated free of charge. "Methods Development" fees shall be assessed, however, if the test substance and/or test system require modifications due to complexity and difficulty of testing.

If the Sponsor requests a repeat test, they will be charged for an additional test.

Neither the name of ATS Labs nor any of its employees are to be used in advertising or other promotion without written consent from ATS Labs.

The Sponsor is responsible for any rejection of the final report by the United States FDA or EPA concerning report format, pagination, etc. To prevent rejection, Sponsor should carefully review the ATS Labs final report and notify ATS Labs of any perceived deficiencies in these areas before submission of the report to the regulatory agency. ATS Labs will make reasonable changes deemed necessary by the Sponsor, without altering the technical data.

JUSTIFICATION FOR SELECTION OF THE TEST SYSTEM

The U.S. Environmental Protection Agency requires that a specific bacterial claim for a sanitizer be supported by appropriate scientific data demonstrating the efficacy of the sanitizer against the claimed bacteria. This is accomplished in the laboratory by treating the target bacteria with the sanitizer (test substance) under conditions which simulate as closely as possible, the actual conditions under which the test substance is designed to be used. For sanitizer products intended for use on non-food contact surfaces, a carrier method is used in the generation of the supporting data. The test system to be used in this study will be a modification of the ASTM approved method for the evaluation of the antimicrobial efficacy of sanitizers on inanimate, nonporous, non-food contact surfaces.

- Proprietary Information -

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Protocol Number: WRA01021808.NFS

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TEST PRINCIPLE

A film of bacterial cells dried on a surface of stainless steel carriers is exposed to the test substance for a specified contact time. After exposure, the carriers are neutralized and assayed for survivors. Appropriate viability, sterility, purity, carrier quantitation and neutralization controls are performed. The current version of Standard Operating Procedure CGT-4150 reflects the methods which shall be used in this study.

TEST METHOD

Test Organisms	ATCC #	Growth Medium	Incubation Parameters
<i>Staphylococcus aureus</i>	6538	AOAC Nutrient Broth	35-37°C, aerobic
<i>Klebsiella pneumoniae</i>	4352	AOAC Nutrient Broth	35-37°C, aerobic

The test organisms to be used in this study were obtained from the American Type Culture Collection (ATCC), Manassas, VA.

Neutralizing Solutions: Solutions appropriate to inactivate sanitizing solutions shall be used.

Carriers

1" x 1" stainless steel surfaces will be prepared by removing the adhesive protective backing, if applicable. Clean each carrier by dipping in ethyl alcohol and rinsing thoroughly in deionized water. After cleaning, decontaminate the surfaces by autoclave sterilization. (Alternatively, the carriers may be decontaminated by dipping in absolute ethanol and aseptically allowing the carriers to dry in a bio-safety hood.) Transfer the carriers aseptically to sterile Petri dishes.

Constant Humidity Chamber (Desiccator)

At least 1 day prior to use, fill the lower portion of a large size desiccator with about 500 mL of glycerin solution (approximately 86.5% glycerin in deionized water). This will provide a constant $40 \pm 2\%$ relative humidity at 35-37°C in which the inoculated glass carrier will be dried prior to treatment with the sanitizer. Replace the floor plate of the desiccator and store at 35-37°C to allow to come to equilibrium. A controlled humidified chamber may be used in place of the desiccator.

Preparation of Inocula

From stock cultures, inoculate tubes of AOAC Nutrient broth. Incubate for 24 ± 2 hours at 35-37°C. Using a 4-mm inside diameter transfer loop, make at least three consecutive daily transfers of cultures in AOAC Nutrient broth prior to use as inoculum. Transfer two loopfuls of culture to 10 mL broth medium. Use transfers which are 4-16 transfers away from stock culture. Use 48 ± 4 hour cultures for the inocula for this test.

Thoroughly mix the 48 ± 4 hour culture of test organism on "vortex" mixer, then allow culture to settle for ≥ 15 minutes. Aspirate the upper two thirds of this suspension and use this as the inoculum for testing. An organic soil load may be added to the test culture per Sponsor's request.

Preparation of Test Substance

The test substance will be prepared according to the directions for intended use of the product. The test substance shall be used within three hours of preparation if additional preparation is required by ATS Labs.

Inoculation of Test and Control Carriers

Inoculate each sterile stainless steel carrier with 0.01-0.03 mL of 48 ± 4 hour culture using a calibrated pipettor. Spread inoculum to within 1/8 inch of the edges of the square. Dry the inoculated carrier at 35-37°C in the constant humidity chamber or desiccator with the lids slightly ajar for *Staphylococcus aureus* and with the lids intact for *Klebsiella pneumoniae*. Allow the carrier to remain at this temperature and humidity for exactly 20-40 minutes.

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Treatment of Inoculated Test Carriers

Following the completion of drying, remove all the plates to room temperature and transfer each carrier to a sterile vessel.

Medicate each carrier using 5.0 mL of the test substance. Expose the carrier to the test substance at room temperature for the Sponsor specified exposure period.

Neutralization and Subculture

Following the Sponsor specified exposure period, transfer 20 mL of the appropriate neutralizer solution to the vessel. Rotate the vessel vigorously on an even plane approximately 50 rotations to suspend the surviving organisms in the neutralizer solution. Continue neutralizing each carrier, using identical staggered intervals, and agitate each in turn. Within 30 minutes after neutralizing the carriers, plate 1.0 mL of the 10^0 and 10^{-1} dilutions of the neutralized solution from each of the vessels in duplicate using the standard spread plate technique and Tryptic Soy agar (or 5% sheep blood agar plates) for all organisms.

Incubation and Observation

Incubate the plates at $35-37^{\circ}\text{C}$ for 48 ± 4 hours prior to observation for number of colonies. If necessary, subculture plates can be stored for up to 3 days at $2-8^{\circ}\text{C}$ prior to examination. Following incubation (or incubation and storage), the plates will be visually enumerated. Representative plates showing growth may be subcultured, stained and/or biochemically assayed to confirm or rule out the presence of the test organism. If possible, subcultures containing 30-300 colonies will be used for calculations.

TEST CONTROLS

Carrier Quantitation Control

Perform the test using inoculated carriers and sterile deionized water in place of test solutions. The inoculated control carriers will be exposed to the sterile deionized water for the identical time and temperature parameters used in the test procedure. Neutralize sterile deionized water as in the test. Prepare ten-fold serial dilutions of the neutralized broth. Plate 1.0 mL of the appropriate dilutions in duplicate to yield countable numbers. Incubate plates as in the test and enumerate. This control will be performed using three carriers. The acceptance criterion for this study control is a minimum geometric mean of 2.0×10^4 CFU/carrier.

Dry Control

An inoculated dry carrier will be added to a vessel containing 20 mL of neutralizing broth and vortex mixed. Prepare ten-fold serial dilutions of the neutralized broth. Plate 1.0 mL of 10^{-1} through 10^{-6} in duplicate to yield countable numbers. Incubate plates as in the test and enumerate. This control is for information purposes only and therefore has no acceptance criterion.

Neutralization Confirmation

A neutralization confirmation control will be performed to demonstrate the neutralizer's ability to inactivate the test substance. The neutralization of the test substance will be confirmed by exposing sterile carriers to the test substance and neutralizing as in the test procedure. Transfer a 1.0 mL aliquot of a diluted suspension of the test organism yielding ≤ 100 CFU/mL of neutralized solution to the vessel and mix. Plate 1.0 mL of this mixed solution in duplicate. Perform a numbers control utilizing a sterile solution in place of the test substance. Incubate the resulting plates as in the test and enumerate. The acceptance criterion for this study control is growth within 1 log₁₀ of the numbers control.

Purity Control

A "streak plate for isolation" will be performed on the organism culture(s) and following incubation examined in order to confirm the presence of a pure culture. The acceptance criterion for this study control is a pure culture demonstrating colony morphology typical of the test organism.

Organic Soil Load Sterility Control

The serum used for the soil load will be cultured, incubated, and visually examined. The acceptance criterion for this study control is no growth.

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Inoculum Count

Prepare and plate serial dilutions of the culture used as the inoculum. Use Tryptic Soy agar (or 5% Sheep Blood agar plate) for all organisms. Incubate the resulting plates for 48±4 hours at 35-37°C and then count the colonies to determine the number of organisms per milliliter of inoculum present at the start of the test. This control is for informational purposes only and therefore has no acceptance criterion.

Neutralizing Subculture Medium Sterility Control

A representative sample of uninoculated neutralizing subculture medium will be incubated and visually examined. The acceptance criterion for this study control is lack of growth.

Carrier Sterility Control

A representative uninoculated carrier will be added to the neutralizing subculture medium. The subculture medium containing the carrier will be incubated and examined. The acceptance criterion for this study control is lack of growth.

Viability Control

A representative inoculated carrier will be added to the subculture medium. The subculture medium containing the carrier will be incubated and visually examined. The acceptance criterion for this study control is growth.

PROCEDURE FOR IDENTIFICATION OF THE TEST SYSTEM

ATS Labs maintains Standard Operating Procedures (SOPs) relative to efficacy testing studies. Efficacy testing is performed in strict adherence to these SOPs which have been constructed to cover all aspects of the work including, but not limited to, receipt, log-in, and tracking of biological reagents including bacterial strains for purposes of identification, receipt and use of chemical reagents. These procedures are designed to document each step of efficacy testing studies. Appropriate references to medium batch number, etc. are documented in the raw data collected during the course of each study.

Additionally, each efficacy test is assigned a unique Project Number when the protocol for the study is initiated by the Study Director. This number is used for identification of the test subcultures, etc. during the course of the test. Test subcultures are also labeled with reference to the test organism, experimental start date, and test product. Microscopic and macroscopic evaluations of positive subcultures are performed in order to confirm the identity of the test organism. These measures are designed to document the identity of the test system.

METHOD FOR CONTROL OF BIAS: N/A

STUDY ACCEPTANCE CRITERIA

Test Substance Performance Criteria

The test substance must meet the EPA efficacy data requirements that a 99.9% reduction in numbers of the test organism(s) was obtained as compared to the carrier quantitation control.

Control Acceptance Criteria

The study controls must perform according to the criteria detailed in the study controls description section.

FINAL REPORT

The report will include, but not limited to, identification of the sample, date received, initiation and completion dates, identification of the bacterial strains used, description of media and reagents, description of the methods employed, tabulated results and conclusion as it relates to the purpose of the test, and all other items required by 40 CFR Part 160.185.

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PROTOCOL CHANGES

If it becomes necessary to make changes in the approved protocol, the revision and reasons for change will be documented, reported to the Sponsor and will become a part of the permanent file for that study. Similarly, the Sponsor will be notified as soon as possible whenever an event occurs that may have an effect on the validity of the study.

Standard operating procedures used in this study will be the current effective revision at the time of the work. Any minor changes to SOPs (for this study) or methods used will be documented in the raw data and approved by the Study Director.

PRODUCT DISPOSITION

It is the responsibility of the Sponsor to retain a sample of the test substance(s). All unused test substance will be discarded following study completion unless otherwise requested by Sponsor.

RECORD RETENTION

Study Specific Documents

All of the original raw data developed exclusively for this study shall be archived at ATS Labs. These original data include, but are not limited to the following:

1. All handwritten raw data for control and test substances including, but not limited to, notebooks, data forms and calculations.
2. Any protocol amendments/deviation notifications.
3. All measured data used in formulating the final report.
4. Memoranda, specifications, and other study specific correspondence relating to interpretation and evaluation of data, other than those documents contained in the final study report.
5. Original signed protocol.
6. Certified copy of final study report.
7. Study specific SOP deviations made during the study.

Facility Specific Documents

The following records shall also be archived at ATS Labs. These documents include, but are not limited to, the following:

1. SOPs which pertain to the study conducted.
2. Non study specific SOP deviations made during the course of this study which may affect the results obtained during this study.
3. Methods which were used or referenced in the study conducted.
4. QA reports for each QA inspection with comments.
5. Facility Records: Temperature Logs (ambient, incubator, etc.), Instrument Logs, Calibration and Maintenance Records.
6. Current curriculum vitae, training records, and job descriptions for all personnel involved in the study.

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Revised: May 15, 2008

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REFERENCES

1. U.S. Environmental Protection Agency, Registration Division, Office of Pesticide Programs, Efficacy Data Requirements Sanitizer Test (for inanimate, non-food contact surfaces), DIS/TSS-10, January 7, 1982.
2. U.S. Environmental Protection Agency Pesticide Assessment Guidelines, Subdivision G, Section 91-2; Item j Sanitizers (for non-food contact surfaces) and Section 91-30(d) (8) Recommended Methods for Sanitizers – Non-food Contact Surfaces.
3. ASTM Test Method, Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces, E1153, July 2003.
4. Official Methods of Analysis of the AOAC, Seventeenth Edition, 2000. Chapter 6 – Disinfectants, 961.02. Germicidal Spray Products as Disinfectants.

DATA ANALYSIS

Calculations

Number of Organisms Surviving per Carrier

$$\text{CFU/carrier} = \frac{(\text{average number colonies/plate @ dilution}) \times (\text{dilution factor}) \times (\text{volume neutralized solution})}{(\text{volume plated})}$$

The carrier population will be calculated and reported using data from the most appropriate dilution(s).

Geometric Mean of Number of Organisms Surviving on Control Carrier:

$$\text{Geometric Mean} = \text{Antilog of } \frac{\log_{10} X_1 + \log_{10} X_2 + \log_{10} X_3}{3}$$

where X equals CFU/control carrier

Geometric Mean of Number of Organisms Surviving on Test Carrier:

$$\text{Geometric Mean} = \text{Antilog of } \frac{\log_{10} Y_1 + \log_{10} Y_2 + \log_{10} Y_3 + \log_{10} Y_4 + \log_{10} Y_5}{5}$$

where Y equals CFU/test carrier

Percent Reduction

$$\% \text{ reduction} = [(a - b) / a] \times 100$$

where:

a = geometric mean of the number of organisms surviving on the inoculated control carriers.

b = geometric mean of the number of organisms surviving on the test carriers.

$$\text{Recovery Log}_{10} \text{ Difference} = (\text{Log}_{10} \text{ Numbers Control}) - (\text{Log}_{10} \text{ Neutralization Results})$$

Used for the neutralization confirmation control

Statistical Methods

Geometric Mean and Percent Reduction

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STUDY INFORMATION

(All sections must be completed prior to submitting protocol)

Sponsor (Date/Initial): 5/27/08 JMM

Test Substance (Name & Batch Numbers, including ≥60 day old batch - exactly as it should appear on final report):
Summit Brands Disposer Care Garbage Disposer Cleaner Sanitizer Disinfectant Lot # 03050UP48,
Lot # 03050UP49 and Lot # 005

Specify ≥60 day old batch: Lot # 005

Expiration Date: 11/19/2008

Product Description:

- | | |
|----------------------------------------------|---------------------------------------------------------------------------------------------|
| <input type="checkbox"/> Quaternary ammonia | <input type="checkbox"/> Peracetic acid |
| <input type="checkbox"/> Iodophor | <input type="checkbox"/> Peroxide |
| <input type="checkbox"/> Sodium hypochlorite | <input checked="" type="checkbox"/> Other <u>sodium dichloro s-triazinetriene dihydrate</u> |

Test Substance Active Concentration (upon submission to ATS Labs): 1.83%

Neutralization/Subculture Broth: ☐

- ☒ ATS Labs' Discretion. By checking, the Sponsor authorizes ATS Labs, at their discretion, to perform neutralization confirmation assays at the Sponsor's expense prior to testing to determine the most appropriate neutralizer. (See Fee Schedule).

Storage Conditions:

- ☒ Room Temperature
☐ 2-8°C
☐ Other: _____

Hazards:

- ☒ None known: Use Standard Precautions
☐ Material Safety Data Sheet, Attached for each product
☐ As Follows: _____

Product Preparation

- ☐ No dilution required, Use as received (RTU)
☒ *Dilutions/Concentrations to be tested see instructions below
☐ Deionized Water (Filter Sterilized)
☐ Tap Water (Filter Sterilized)
☒ AOAC Synthetic Hard Water: 400 PPM
☐ Other: _____

*Note: An equivalent dilution may be made unless otherwise requested by the Sponsor.

Test Organism(s): ☒ Staphylococcus aureus (ATCC 6538)
☒ Klebsiella pneumoniae (ATCC 4352)

Carrier Number: 5 test carriers and 3 control carriers

Exposure Time: 30 Seconds

Exposure Temperature: Room temperature

Organic Soil Load:

- ☒ Minimum 5% Organic Soil Load (Fetal Bovine Serum)
☐ No Organic Soil Load Required
☐ Other: _____

USE DILUTION INSTRUCTIONS - Dissolve the contents of one packet in 16 fluid ounces of AOAC Synthetic hard water heated to 48-51°C. Mix the solution in a large flask using a sterile bar for 3-4 minutes. Cut up the packet into 1/4 by 1/4 inch squares and add to the flask. Continue to stir briefly to thoroughly incorporate the the packet and any remaining powder. Allow the foaming to subside for 3-4 minutes. Prepared product should be made immediately prior to medication of test carriers. Entire preparation of the test substance should take approximately 10 minutes.

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TEST SUBSTANCE SHIPMENT STATUS

- ☐ Has been used in one or more previous studies at ATS Labs.
☒ Has been shipped to ATS Labs (but has not been used in a previous study).
Date shipped to ATS Labs: _____ Sent via overnight delivery? ☐ Yes ☐ No
☐ Will be shipped to ATS Labs.
Date of expected receipt at ATS Labs: _____
☐ Sender (if other than Sponsor): _____

COMPLIANCE

Study to be performed under EPA Good Laboratory Practice regulations (40 CFR Part 160) and in accordance to standard operating procedures.

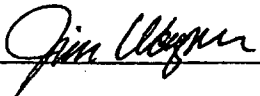
- ☒ Yes
☐ No (Non-GLP Study)

PROTOCOL MODIFICATIONS

- ☒ Approved without modification
☐ Approved with modification - Supplemental Information Form Attached - ☐ Yes ☐ No

APPROVAL SIGNATURES

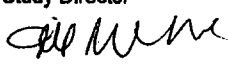
SPONSOR:

NAME: Jim Wagner (Summit Brands) TITLE: Agent for Summit Brands
SIGNATURE:  DATE: 5/27/08
PHONE: 302-234-8550 FAX: 302-234-7570 EMAIL: james@wagnerreg.com

For confidentiality purposes, study information will be released only to the sponsor/representative signing the protocol (above) unless other individuals are specifically authorized in writing to receive study information.

Other individuals authorized to receive information regarding this study: ☐ See Attached

ATS Labs:

NAME: Jill Rukme
Study Director
SIGNATURE:  DATE: 6-12-08
Study Director

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